October 14, 2025

Dawell Medical LLC.
% Diane Horwitz
Regulatory
TAG3 Engineering
1161 Sawgrass Corporate Parkway
Sunrise, Florida 33323

Re: K250776
Trade/Device Name: Lithoblast Single-Use Holmium Laser Fibers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 13, 2025
Received: March 14, 2025

Dear Diane Horwitz:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

YAN FU -S Digitally signed by YAN FU -S
Date: 2025.10.14 07:51:37 -04'00'

for Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250776

Device Name
Lithoblast Single-Use Holmium Laser Fibers

Indications for Use *(Describe)*
The LithoBlast Single-Use Holmium Laser Fiber is indicated for use in surgical specialties in which a compatible Ho:YAG laser system has received regulatory clearance. LithoBlast surgical fiber optic laser delivery devices are intended for use with any open source cleared surgical laser with an SMA 905 connector.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DAWELL™ MEDICAL

K250776

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

Dawell Medical LLC
18505 SW 104th Ave., Unit 25
Miami, FL 33157

1.2 Official Correspondent

Diane Horwitz, Ph.D.
Regulatory, TAG3 Engineering
1161 Sawgrass Corporate Parkway
Sunrise FL 33323
Phone (703) 307-2921
E-mail: dhorwitz@tag3engineering.com

1.3 Date of Preparation

October 10, 2025

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

LithoBlast Single-Use Holmium Laser Fibers

2.1.2 Common/Usual Name

Powered Laser Surgical Instrument

2.1.3 Classification Information

Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Regulation:	21 CFR 878.4810
Class:	II
Product Code:	GEX
Panel:	General Surgery Devices (DHT4A)

3. PREDICATE DEVICE

The predicate device is the Laser Peripherals Family of Laser Fibers, K170366, Laser Peripherals LLC.

4. DESCRIPTION OF THE DEVICE

The LithoBlast Single-Use Holmium Laser Fibers are single use surgical fiberoptic laser delivery devices that transmit laser energy in a forward direction. The devices include a SMA 905 connector at the proximal end. The laser fibers are compatible with Ho:YAG laser systems. There are four (4) fiber core diameters: 272 Series (272 µm), 365 Series (365 µm), 550 Series (550 µm), and 940 Series (940 µm).

The laser fibers in the LithoBlast family are 300cm long. All have a 10 mm straight cut flat cleaved distal end. All include a stress booth and an ABS over nut extension sleeve (type A=straight and narrow; type B=indented with finger grips; type C=finger grips protrude) to enable the operator's firm grip. The SMA-905 connector attaches at the proximal end of the device.

5. INTENDED USE

The intended use / indications for use for the LithoBlast Single-Use Holmium Laser Fibers is as follows:

> The LithoBlast Single-Use Holmium Laser Fiber is indicated for use in surgical specialties in which a compatible Ho:YAG laser system has received regulatory clearance. LithoBlast surgical fiber optic laser delivery devices are intended for use with any open source cleared surgical laser with an SMA 905 connector.

6. INTENDED USE COMPARED TO THE PREDICATE

The intended use of the subject and predicate are the same aside from the product name. The indication for use of the subject device is a subset of the predicate device.

7. TECHNOLOGY CHARACTERISTICS COMPARED TO THE PREDICATE

The LithoBlast Laser Fiber Models include those with SMA 905 connector, core fiber sizes from 272 to 940µm, and a straight cut flat cleaved distal end. The models selected for development by Dawell Medical are technologically comparable to the similar predicate models.

	LithoBlast Single-Use Holmium Laser Fibers **Subject Device**	**Laser Peripherals Family of Bare Laser Fibers K170366** **Predicate Device**	**Similar or Different**
Product Code Regulation	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810	Same
Regulation Name	Laser surgical instruments for use in general plastic surgery and dermatology	Laser surgical instruments for use in general plastic surgery and dermatology	Same
Compatible Lasers and Connectors	FDA Cleared Ho: YAG laser systems (2000 to 2200 nm) with SMA 905 connectors	FDA Cleared lasers (550 to 2200 nm) with SMA 905 or SMA 906 connector	Similar; Subset of predicate
Core OD (µm)	272, 365, 550, 940	150, 200, 272, 365, 550, 600, 800, 940, 1000	Similar; Subset of predicate

	LithoBlast Single-Use Holmium Laser Fibers Subject Device	Laser Peripherals Family of Bare Laser Fibers K170366 Predicate Device	Similar or Different
Operating power ranges W	272 µm – 0-20W 365 µm – 0-40W 550 µm – 0-80W 940 µm – 0-80W	150 µm - 0-8W 200 µm - 0-45W 272 µm - 0-45W 365 µm – 0-100W 550 µm – 0-200W 940 µm – 0-200W 1000 µm – 0-200W	Similar; Operates within the range of the predicate
Fiber	Standard silica core fiber w/silica cladding, w/fluoropolymer coating, w/acrylate, Teflon, nylon, or polyimide buffer	Standard silica core fiber optic w/fluoropolymer hard cladding, w/acrylate, Teflon, nylon, or polyimide buffer Standard silica core fiber w/silica cladding, w/fluoropolymer coating, w/acrylate, Teflon, nylon, or polyimide buffer	Same as predicate
Jacket	Teflon, Peek, or similar sleeve provided for protection during handling	Teflon, Peek, or similar sleeve provided for protection during handling	Same
Numerical Aperture (NA) of Silica/ Hard clad fibers (µm)	0.22 ± 0.02	Between 0.22 and 0.48	Similar; Subset of predicate
Fiber distal tip	Flat	Multiple configurations including flat	Similar; Subset of predicate

8. PERFORMANCE TESTING

Bench performance tests, biocompatibility and sterilization and packaging validation support the substantial equivalence between the LithoBlast laser fiber family and the predicate device.

Performance tests included:

- Power transmission, initial and long duration
- Connection temperature
- Aiming beam
- Dimensional specifications and surface finish
- Trackability and kink radius
- Fiber control, torqueability
- Tensile strength
- Compatibility

9. CONCLUSIONS

The nonclinical testing in this 510(k) leads to the conclusion that the LithoBlast Single-Use Holmium Laser Fiber is as safe, as effective, and performs as well as or better than the legally marketed predicate device per 21 CFR 807.92(b)(3).